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10/680,905

10/07/2003

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7590 05/12/2009
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EXAMINER

CAMERON, ERMA C

ART UNIT

PAPER NUMBER

1792

MAIL DATE

DELIVERY MODE

05/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/680,905 | Applicant(s) PACETTI ET AL. | |
| | Examiner /Erma Cameron/ | Art Unit 1792 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2008 and 30 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-9,12-15,17,18,20-23,41,42,45,47,51,52,54 and 58 is/are pending in the application.
- 4a) Of the above claim(s) 9,14,17,18,20-23,41,42,54 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,12,13,15,45,47,51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Election/Restrictions

1. Applicant's election with traverse of species a) in the reply filed on 1/30/2009 is acknowledged. The traversal is on the ground(s) that there is no burden on the examiner. This is not found persuasive because each of the species a) and b) is a separate coating method and would require separate searches and considerations. This creates a serious burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 17-18, 20-23 and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/30/2009.

3. Applicant's election with traverse of Group I and species a) and d) in the reply filed on 9/22/2008 is acknowledged. The traversal is on the ground(s) that there is not a serious burden on the examiner. This is not found persuasive because Group I is an applicator method and

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Group II is a submerging or immersing method. These two methods are quite distinctive, and would require separate searches. In addition, the species elected within Groups A and B are also distinctive, and would require separate searches. All of these separate searches are a serious burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 9, 14, 41 and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/22/2008.

NOTE: THE APPLICANT HAS INDICATED IN THE 1/30/2009 RESPONSE THAT CLAIM 15 IS BOTH WITHDRAWN AND CURRENTLY AMENDED. THIS IS INCORRECT. CLAIM 15 IS NOT WITHDRAWN.

NOTE: THE CLAIMS THAT ARE BEING EXAMINED ARE BASED ON THE 9/22/2008 AMENDMENT, AS WELL AS THE AMENDMENT TO CLAIM 15 ENTERED IN THE 1/30/2009 RESPONSE.

Claims 1-3, 5-8, 12-13, 15, 45, 47 and 51-52 have been examined

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 12, 15, 47 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is new matter that was not in the specification as filed (from 7/8/2008 office action):

| | |
|----------|---------------------------------------|
| Claim 1 | rejection is withdrawn |
| Claim 12 | original rejection is withdrawn |
| Claim 18 | claim is withdrawn from consideration |
| Claim 21 | claim is withdrawn from consideration |
| Claim 23 | claim is withdrawn from consideration |
| Claim 46 | claim is canceled (9/28/2008) |

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Claim 47 the rejection is maintained

Claim 52 the rejection is maintained

Claim 53 claim is canceled (9/28/2008)

Claim 55 claim is canceled (9/28/2008)

Claim 56 claim is canceled (9/28/2008)

Response to Arguments

Claim 47 the applicant has argued that support is found at [0049]. The examiner disagrees. [0049]/Figure 10 do not illustrate rotating the applicator over the length of the device; rather, the applicator is being rotated around the circumference of the device.

Claim 52 the applicant has not argued this rejection. It is the examiner's position that this claim is not supported by the specification. References to the applicator and stent rotating at similar speeds, such as at [0047] are in reference to coating that goes along the circumference of the stent, not along the length of the device, as claimed in claim 1.

New rejections:

Claim 12 200 rotations (the examiner's position is that [0047] does not refer to applying a coating along the length of the stent)

Claim 15 "metering roller" ([0049]/Figure 10 do not refer to a coating that is applied along the length of the stent)

The applicant is requested to cancel all new matter.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 13, 15, 47 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 13: it appears that the wording should be “the rotating of the applicator step”.

b) Claim 13: here is no antecedent basis for “the applicator step”.

c) Claim 15, line 3: there is no antecedent basis for “the metering roller”.

d) Claim 47: it is not clear where the direction is being viewed from.

e) Claim 51: it is not clear when the submerging occurs.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. The rejection of Claims 1, 5, 7-8, 13, 15-18, 20, 22-24, 47 and 49-51 under 35

U.S.C. 102(e) as being clearly anticipated by Shekalim et al (6971813) is withdrawn because of the amendment filed 1/30/2009.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-3, 5-8, 12-13, 15, 47 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shekalim et al (6971813).

‘813 teaches applying a polymer and drug coating to a roller from a reservoir or sponge and rotating the roller in one direction while the stent it contacts rotates in the other direction, thus applying the coating to the stent. A wiper 18 may limit and level the coating on the roller. The application surface may be flat or curved (see Figures 1-4, 8:50-9:34, 10:38-13:48). The rollers can move laterally over the surface of the stent or around the stent, and these movements can be coordinated with movement of the stent (10:65-11:1).

‘813 does not teach the viscosity of the coating composition, the rate of revolution of the stent and roller, or the thickness of the coating on the roller, but it would have been obvious to one of ordinary skill in the art to have optimized these parameters through no more than routine experimentation as they are known to be parameters that will affect the coating quality.

Response to Arguments

Regarding the arguments for claim 1: the applicant has argued that ‘813 does not teach applying a first stripe and then a second stripe after rotating the device. The examiner disagrees. The Figures 1-4 illustrate several ways to coat one area of the stent at a time. In particular, Figure 1 illustrates “rollers can move laterally over the surface of the prosthesis or around the prosthesis. Both of these movements of the rollers can be coordinated with movement of the prosthesis”. (10:65-11:1) One of skill in the art would know that the same surface was not being coated over and over; rather, the applicator is moved from area to area of the stent, either by movement of the applicator or movement of the stent, as taught by ‘813.

Regarding the arguments for claim 18: claim 18 has been withdrawn from consideration.

13. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shekalim et al (6971813) taken in view of Pinchuk et al (5968091).

‘813 is applied here for the reasons given above.

‘813 teaches that the stent rotates while coating material is applied to it (10:54-60), but does not teach how the rotation occurs.

‘091 teaches that a mandrel may be used to rotate a stent while it is being coated (Example 9).

It would have been obvious to one of ordinary skill in the art to have used the mandrel of ‘091 in the ‘813 coating process to rotate the stent, because of the teaching of ‘091 that a mandrel is a conventional method of rotating a stent.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Erma Cameron/ whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erma Cameron/

Primary Examiner

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May 11, 2009